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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/338,221	06/22/1999	ELI PINES	11658/10	1129

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EXAMINER	
GUPTA, ANISH	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 08/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/338,221	PINES ET AL.	
	Examiner	Art Unit	
	Anish Gupta	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *19 May 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14 and 35-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14 and 35-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed 5-19-04 is acknowledged. Claims 7, 1, 36 were amended. Claims 1-14 and 35-51 are pending in this application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

2. Claims 1-14 and 35-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tripodi e al.

Applicants argue that the reference does not teach or suggest determination of the percent of fibrinogen that is clottable in the composition. Applicants assert that there are "numerous reasons why at least a portion of the fibrinogen molecule derived from a purification process therefor may not be clottable, including denaturation." Moreover, the presence of residual amounts and types of blood plasma proteins (co purified with the

fibrinogen) that are present in the therapeutic composition. Applicants also assert that there is no basis to conclude that the amount of clottable fibrinogen is 56% or greater since it is not certain that the mere presence of 90-98% fibrinogen leads to the same percentage of clottable fibrinogen.

Applicants also state that Tripodi et al. does not disclose "the recovered fibrinogen polymerizes when provided in a solution at said site at a therapeutically effective fibrinogen concentration of about 10 mg/ml thereof or less." There is no disclosure of such a limitation in the reference and thus there is "no basis upon which to conclude that the composition described by Tripodi possesses such low concentration at the treatment site which polymerizes at said site to a fibrin network having therapeutically effective strength, as presently claimed." Tripodi does not disclose the use of a such low concentrations at the treatment site. Finally, Applicants argue that Tripodi does not teach the rapid rate of reconstitution of the composition described in the application, nor is there anything in Tripodi's disclosure which would lead one of skill in the art to arrive at this feature with an expectation of success.

Applicant's arguments filed 5-19-04 have been fully considered but they are not persuasive.

The MPEP states that "[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on inherency' under 35 U.S.C. 102, on prima facie obviousness' under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted]." The burden of proof is similar to that required with respect to product-by-process claims. In re Fitzgerald, 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) (quoting In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977)).

Here, as stated in the previous office action, the Tripodi teaches the claimed invention. The reference discloses a "fraction procedure described produces a composition containing at least about 90 to about 98 percent fibrinogen with a low level of conversion to fibrin." (see page 8, lines 25-34). Note that the instant claims also recite that the composition contains at least 90% fibrinogen. The reference states that the composition can be formulated in a lyophilized powder and can be used at a concentration of between 1 to 40 mg/ml of fibrinogen (see page 10, lines 22-33), much like the claimed invention. The reference further teaches that a buffer system comprising sodium citrate and epsilon amino caproic acid at a concentration of .009 M and .1 M respectively can be used as a reconstitution buffer (see page 9, lines 1-12). Note that this concentration is well within the range claimed in claim 3 and 4 of the instant application (using stoichiometric conversion .009M sodium citrate equates to ~2.322 mg and .1M aminocaproic acid equates to ~10.3 mg's.). Further, the reference discloses that the composition taught, much like the composition claimed in the claimed invention, is useful in wound closure that is effective on contact with thrombin. Thus, the reference discloses a therapeutic fibrinogen composition with the same concentration of fibrinogen which is used for the same purpose. Since the composition comporises the same source of clottable fibrinogen and is used for the same purpose as the claimed invention, there is sufficient reasonable basis to conclude that the reference composition contains about 56% clottable fibrinogen. Applicants have not met their burden of proof to establish that the products are different and the reference composition does not contain 56% clottable fibrinogen. In their response, Applicants have speculated as to the conditions that might prevent 56% clottable fibrinogen. However, these are mere speculations. The MPEP states "[t]he arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA

1965); In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997) ("An assertion of what seems to follow from common experience is just attorney argument and not the kind of factual evidence that is required to rebut a prima facie case of obviousness."). Here, Applicants have provided only assertions made by counsel and not factual evidence to rebut the rejection.

As for arguments with regards to concentration and rapid reconstitution, this portion of the claim is preceded by a "wherein" clause. Wherein clauses and whereby clauses that merely state the result of the limitations in the claims adds nothing to the patentability or substance of the claim. Here the wherein clause only states a result of the composition at 10mg/ml. That is, at a composition is effective at a concentration of 10 mg/ml at the site of treatment and polymerizes at this concentration. The disclosed composition in Tripodi et al. would necessarily achieve this result since the product is the same as the claimed invention. Applicants have not provided any evidence to rebut this assertion. It should be noted that the reconstitution buffer recited in the reference is similar to the claimed invention.

The rejection is maintained.

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee

pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (571)272-0965. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can normally be reached on (571) 272-0974. The fax phone number of this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Anish Gupta 8/5/04
Patent Examiner

BRUCE R. CAMPELL, PH.D
SUPERVISORY PATENT EXAMINER
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